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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,621	12/27/2001	Peter C. Meltzer	70207/56,579	9295
21874	7590	10/06/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			AULAKH, CHARANJIT	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,621

Applicant(s)

MELTZER ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 33-35, 37 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31, 33-35, 37 and 39-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on Aug. 2, 2004, the applicants have canceled claims 32, 36 and 38 and furthermore, have amended claims 1, 14, 17 and 20.
2. Claims 1-31, 33-35, 37 and 39-45 are now pending in the application.

Response to Arguments

3. Applicant's arguments filed on Aug. 2, 2004 have been fully considered but they are not persuasive regarding enablement, most of indefiniteness rejections and prior art rejections. In regard to enablement, the examiner does not agree with the applicants arguments that it is well known in the prior art that deficiency of serotonin and /or dopamine is implicated in the etiology of every known neurodegenerative disease, psychiatric disease, dopamine dysfunctions, cocaine abuse and clinical dysfunctions. There is no teaching either in the specification or prior art that serotonin uptake and/or dopamine uptake inhibitors are efficacious in known animal models of every known neurodegenerative disease, psychiatric disease, dopamine dysfunctions, cocaine abuse and clinical dysfunctions.

In regard to indefiniteness rejections, the examiner does not agree with the applicants arguments that claims 25-28 are clear and furthermore, the term ---clinical dysfunction-- is definite. What is the difference between inhibiting serotonin uptake and inhibiting serotonin transporter? Also, serotonin uptake will not be inhibited by contacting the compound with other monoamine transporters such as dopamine and norepinephrine. The applicants mention that inhibition can be achieved in vitro or in vivo. However, claim language does not suggest this. In regard to clinical dysfunction, the examiner does not

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agree with the applicants arguments that this is a definite term known in the prior art. According to applicants arguments, clinical dysfunction covers every possible known disease in the art since it refers to --- any abnormality or disturbance in the function of an organ, tissue, cell, or a part of cell, in an individual----- and therefore, the instant compounds will have utility in treating every possible known disease in the art. The examiner does not agree with this.

In regard to prior art rejections, the applicants have amended specification to claim priority to earlier date. However, the applicants are not entitled to this priority date since applicants have not met all the conditions (see MPEP 201.11, III and 37 CFR 1.78(a)(2)(ii)).

Conclusion

4. Rejections of claims 30, 31, 33-35, 37 and 39-43 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
5. Rejections of claims 25-28, 30, 31 and 42 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
6. All prior art rejections under 35 U.S.C. 102(a), 102(b) and 102(e) are maintained for the reasons of record.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
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